

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

IN RE SELENIOUS ACID LITIGATION

C.A. No. 2:24-11503-BRM-CLW

**CONSENT JUDGMENT**

American Regent, Inc. ("ARI"), and Amneal Pharmaceuticals of New York, LLC and Amneal EU, Limited (collectively, "Amneal"), parties in the above-captioned action, specifically in the action initiated by Plaintiff. ARI, against Amneal in Civil Action No. 2:2411503 (BRM)(CLW), have resolved this litigation for good cause and valuable consideration recognized by ARI and Amneal. Now the parties, by their respective undersigned attorneys, hereby stipulate and consent to entry of judgment and an injunction in the action, as follows:

IT IS this \_\_\_\_\_ day of \_\_\_\_\_, 2025:

ORDERED, ADJUDGED AND DECREED as follows:

1. This District Court has jurisdiction over the subject matter of the above action and has personal jurisdiction over the parties.
2. As used in this Consent Judgment, (i) the term "Amneal Product" shall mean the drug product manufactured, sold, offered for sale or distributed pursuant to Abbreviated New Drug Application No. 219069 (including any supplements or modification or amendments thereto or replacements thereof) ("Amneal's ANDA"); (ii) the term "Licensed ARI Patents" shall mean United States Patent Nos. 11,998,565 ("the '565 patent") and

12,150,957 ("the '957 patent"); and (iii) the term "Affiliate" shall mean any entity or person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with Amneal; for purposes of this definition, "control" means: (a) ownership, directly or through one or more intermediaries, of: (1) more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or (2) more than fifty percent (50%) of the equity interests in the case of any other type of legal entity or status as a general partner in any partnership; or (b) any other arrangement whereby an entity or person has the right to elect a majority of the Board of Directors or equivalent governing body of a corporation or other entity or the right to direct the management and policies of a corporation or other entity.

3. Unless otherwise specifically authorized by ARI pursuant to the Settlement Agreement or by 35 U.S.C. § 271(e)(1), Amneal, including any of its Affiliates, successors and assigns, is enjoined from infringing the Licensed ARI Patents, on its own part or through any Affiliate, by making, having made, using, selling, offering to sell, importing or distributing of the Amneal Product in the United States.

4. Compliance with this Consent Judgment may be enforced by ARI, its successors in interest, or assigns, as permitted by the terms of the Settlement Agreement.

5. This District Court retains jurisdiction to enforce or supervise performance under this Consent Judgment and the Settlement Agreement.

6. All claims, counterclaims, affirmative defenses and demands in this action are hereby dismissed without prejudice and without costs, disbursements or attorneys' fees to any party.

7. Nothing herein shall preclude the U.S. Food & Drug Administration from granting final approval to Amneal's ANDA or shall preclude Amneal from filing, modifying, or

maintaining with the FDA any Paragraph IV Certification for the Amneal Product pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Brian R. Martinotti  
UNITED STATES DISTRICT JUDGE

We hereby consent to the form and entry of this Order:

s/ Charles H. Chevalier

Charles H. Chevalier  
GIBBONS P.C.  
One Gateway Center  
Newark, New Jersey 07102-5310  
(973) 596-4611  
cchevailier@gibbonslaw.com

Christine A. Gaddis  
GIBBONS P.C.  
141 West Front Street, Suite 240  
Red Bank, New Jersey 07701  
(732) 704-5801  
cgaddis@gibbonslaw.com

OF COUNSEL:

Dennies Varughese, Pharm. D.  
Uma Everet  
Adam LaRock  
Alex Alfano  
Ryan Conkin  
Sterne, Kessler, Goldstein & Fox  
P.L.L.C.  
1101 K Street, NW, 10th Floor  
Washington, DC 20005  
(202) 371-2600  
dvarughese@sternekessler.com  
ueverett@sternekessler.com  
alarock@sternekessler.com  
aalfano@sternekessler.com  
rconkin@sternekessler.com

*Attorneys for Plaintiff  
American Regent, Inc.*



Jeremy Edwards  
Steven Maddox  
PROCOPIO  
1901 L Street NW, Suite 620  
Washington, DC 20036  
(202) 830-0540  
Jeremy.edwards@procopio.com  
Steven.Maddox@procopio.com

*Attorneys for Defendants  
Amneal Pharmaceuticals of New  
York, LLC and Amneal EU, Limited*